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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,032	11/20/2003	Timothy A. Geiser	ACS 58145 (3166P)	2537

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,032	GEISER ET AL.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,18 and 24-36* is/are pending in the application.

4a) Of the above claim(s) *2 and 4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7,8,18 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/14/05,11/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I (apparatus directed to claims 1-18), species a. (depicted in Figures 1-3, claims 1, 3, 4, 8, 9, 18, 24-36) in the reply filed on 03/15/07 is acknowledged.

2. Claims 2 and 5-7 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/15/07.

Drawings

3. The drawings are objected to because in Fig. 1, indicating numbers (42) and (56) appear to be indicating the same part. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 3 is objected to because of the following informalities: It is suggested that the limitation "proximal portion" should be further clarified by stating that it is the proximal portion of inner member. Appropriate correction is required.

5. Claim 26 is objected to because of the following informalities: The limitation (starting at line 11) "the outer catheter member having a distal portion adapted to at least partially cover the medical device and a proximal end attached to the control handle" is unclear. Examiner is unable to determine whether the proximal end refers to the proximal end of the outer catheter is attached to the control handle or whether the proximal end of the distal portion is attached to the control handle. Appropriate correction is required.

6. Claim 27 is objected to because of the following informalities: There is lack of antecedent basis for the limitation "guide wire restraining member". Appropriate correction is required.

7. Claim 27 is objected to because of the following informalities: Typo: "member remains is slidably". Appropriate correction is required.

8. Claim 32 is objected to because of the following informalities: it is unclear how the guidewire receiving member extends into the proximal opening of the intermediate

portion. In Fig. 1 the guidewire receiving member is inside the lumen created by the intermediate member, but it is not shown extending into (or out of) the proximal opening or the opening of the tube that is at the proximal end. Therefore it is unclear what applicant is intending to be the proximal opening and how far into the lumen the proximal opening extends. The specification offers no guidance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 4, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a catheter with an inner member, guidewire receiving member, and outer member, does not reasonably provide enablement for "the outer member having a distal opening in communication with the guidewire receiving member". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Since the guidewire receiving member (42) is enclosed by the tubular component (56), it is not understood how the distal opening of the outer member is in communication with the guidewire receiving member.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1, 3, 4, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the "the outer member having a distal opening in communication with the guidewire receiving member", since the guidewire receiving member (42) is enclosed by the tubular component (56).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 25-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (USPN 5,792,144).

15. Fischell discloses a catheter assembly (see entire document) comprising: a control handle (6); an inner catheter member including a distal mounting portion (defined by 71 and 23) adapted to have a medical device mounted thereon (40), a proximal portion (see 11 and 12, fig. 1) having a proximal end attached to the control handle, and a guide wire receiving member (63/65, Fig. 7) for receiving a guide wire

(50), the guide wire receiving member being attached to the proximal portion of the inner catheter member (Col 7, lines 51-57 state that the metal joining tube (73) joins the guidewire lumen (65) to the shaft (72/12), the guide wire receiving member having a proximal end with an opening (66) and a distal end with an opening (19), a lumen (65) extending between these openings formed on the distal and proximal ends of the guide wire receiving member; and an outer catheter member (30) co-axially disposed over the inner catheter member and dimensioned for relative axial movement relative to each other, the outer catheter member having a distal portion (36) adapted to at least partially cover the medical device and a proximal end of the outer catheter attached to the control handle (Fig. 1), the outer catheter member being movable by the control handle to uncover the medical device, the outer catheter member including a proximal portion (32) having a lumen for receiving at least a portion of the inner catheter member and an intermediate portion (34) having a lumen through which the guide wire receiving member extends, wherein the proximal portion of the outer catheter member is attached to and extends into the lumen of the intermediate portion (see portion of Fig. 1 where arrow is 30 and note how 32 is connected to 34)) and the distal portion of the outer catheter member is attached to the intermediate portion. The proximal end of the guidewire receiving member, which does not extend through the lumen of the distal mounting portion is slidably disposed within the lumen of the intermediate portion of the outer catheter member. The distal mounting portion of the inner catheter member has a lumen (formed by (71) and (23)) and a portion of the guide wire member extends through the lumen (see Fig. 1 and 7). The guidewire member is secured to the wall (71)

of the lumen at location (73). The lumen of the intermediate portion has a proximal opening (62) and the guidewire member extends into the opening.

16. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Vrba (USPN 6,254,609).

17. Vrba discloses a sheath for restraining a self-expanding stent on a catheter assembly, the sheath comprising a tubular body having an inner surface (140) which directly contacts the self-expanding stent (168) and an outer surface (144), the tubular body being made from a layer of polyimide to form the inner surface (Col 6, line 4) and a layer of nylon (Col 5, line 64) covering the layer of polyimide.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 3, 4, 24, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Cummings (USPN 6,736,839).

20. Fischell discloses the invention substantially as claimed as stated above except for the proximal portion being formed from a hypotube.

21. Cummings discloses a stent delivery device incorporating a sheath where in a hypotube is the proximal portion of the sheath or outer member. (Col 3, line 60-67)

22. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hypotube into the proximal portion of the Fischell device since it is well known in the art to use hypotubes for increased strength and pushability. It is well known in the art that hypotubes are made form stainless steel or nickel-titanium. With the incorporation of a hypotube, the proximal portion will inherently be less flexible than the intermediate portion.

23. **Claims 8, 9, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Wilson (USPN 6,019,778) and further in view of Vrba (USPN 6,254,609).**

24. Fischell discloses the invention substantially as claimed as stated above except for the sheath portion being made from a nylon-coated polyimide.

25. Wilson discloses a sheath with an outer layer that is preferably nylon and an inner layer that is preferably PTFE. (Col 6, line 33-39)

26. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sheath with a nylon outer layer and a PTFE inner layer since Wilson discloses that this is a preferable combination of materials for a sheath in a stent deliver device. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

1. Fischell in view of Wilson does not disclose that the inner layer is a polyimide but rather a PTFE.

2. Vrba discloses that it is well known to substitute polyimide for PTFE as an inner layer of a sheath that is in direct contact with a stent.

3. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate polyimide into the inner layer of the sheath in place of PTFE. Fischell in view of WIlson discloses the claimed invention except for PTFE instead of polyimide. Vrba shows that polyimide is an equivalent material known in the art. Therefore, because the two materials were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the polyimide for PTFE.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
5/29/07.